ISRCTN12201059 https://doi.org/10.1186/ISRCTN12201059

Proper understanding of recurrent stress urinary incontinence treatment in women

Submission date
17/12/2019

Recruitment status
No longer recruiting

Registration date
09/01/2020

Overall study status
Stopped

Last Edited
24/11/2023

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Urinary leakage with physical activity is called stress urinary incontinence (SUI), and it affects about a quarter of women after pregnancy. Until recently, the most common treatment was a surgical operation which helps to support the tube which takes urine from the bladder to the outside (urethra), called midurethral (mesh) tape. Unfortunately, symptoms can come back after treatment, this is called recurrent SUI. In some cases, symptoms may never have gone away, this is called persistent SUI. Current treatment options for recurrent or persistent SUI include:
1. Injections into the urethra to help it to seal when leaks might happen called endoscopic bulking injections. The injections are done from a tube outside the body.
2. Surgical operations include:
- A medical mesh tape is placed in the vagina to support the urethra (midurethral tape)
- A strip of the patient's own tissue (taken from the tummy area) is used to support the urethra (autologous fascial sling)
- Stitches are used to lift the vagina so that it supports the urethra (colposuspension)
- An implant device is placed around the urethra to gently squeeze it and prevent leaking (artificial urinary sphincter)
It is not known which of these treatments is best for women who have already had an operation or injections for SUI. The aim of this study is to find out whether surgical operations or endoscopic bulking injections are better for treating recurrent or persistent SUI.

Who can participate?
Adult (18 years or older) women with recurrent or persistent SUI who have already had an operation or bulking injection for it

What does the study involve?
250 women are recruited to the study. Equal numbers of women join an endoscopic bulking injection group or a surgical operation group. Which group women join will be decided by chance (in a process called randomisation). Women in the surgical operation group decide which operation to have with their doctor. Women receive their treatment and aftercare at hospital as they would during normal NHS care and are asked to complete a questionnaire booklet at the start of the study and again 6 months, 1, 2 and 3 years later. The questionnaires cover general health, urinary symptoms and the effect of those symptoms on everyday life and sex life. The

researchers audio-record consultations where the study is discussed with women and interview some women to see how research is explained and understand how women manage after their treatment.

What are the possible benefits and risks of participating?
Some people enjoy being part of research studies because of the close contact with research staff and the opportunity to share their opinions and experiences of their condition and treatments. Women will be offered a £10 voucher for completing their questionnaire at 1 year and another £10 voucher for completing their questionnaire at 3 years. There is no additional risk to normal NHS practice of the endoscopic bulking injections or surgical operations, and neither are new or experimental. Women taking part will have the same risks as anyone having treatment for recurrent SUI. This includes the possibility that symptoms may not improve as much as women would like. The risks and benefits of each treatment will be explained by the doctors, and women will be provided with relevant hospital leaflets.

Where is the study run from?
This study is sponsored by North Bristol NHS Trust. The Bristol Randomised Trials Collaboration (as part of the Bristol Trials Centre) at the University of Bristol is responsible for managing the study. The researchers aim to run the study in 20 NHS hospitals across the UK.

When is the study starting and how long is it expected to run for?
April 2019 to October 2022

Who is funding the study?
National Institute of Health Research (NIHR) Health Technology Assessment (HTA) Programme (UK)

Who is the main contact?
Dr Caroline Pope
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Study website
https://pursuit.blogs.bristol.ac.uk/

Contact information

Type(s)
Public

Contact name
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
257547

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Sponsor reference: #4404, HTA 17/95/03, IRAS ID 257547

Study information

Scientific Title
Proper Understanding of Recurrent Stress Urinary Incontinence Treatment in women (PURSUIT): a randomised controlled trial of endoscopic and surgical treatment

Acronym
PURSUIT

Study objectives
To determine whether surgical treatment is superior to endoscopic bulking injections in terms of symptom severity at 1-year after randomisation, in women with recurrent SUI.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 19/12/2019, South West - Frenchay Research Ethics Committee (Level 3, Block B, Whitefriars, Lewins Mead, Bristol, BS1 2NT, UK; Tel: +44 (0)207 1048 045; Email: nrescommittee.southwest-frenchay@nhs.net), ref: 19/SW/0209

Study design
Two-arm multi-centre interventional randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a Participant Information Leaflet.

Health condition(s) or problem(s) studied
Recurrent or persistent Stress Urinary Incontinence (SUI)

Interventions
Participants will be randomised on a 1:1 basis using an online randomisation system or automated telephone system:
Arm 1 - endoscopic (urethral) bulking injections
Arm 2 - surgical procedure (colposuspension or autologous urethral sling or midurethral tape or artificial urinary sphincter (AUS)); women in the surgical operation group will decide which operation to have with their doctor

Women will receive their treatment and aftercare at hospital, as they would during normal NHS care and will be asked to complete a questionnaire booklet at the start of the study and again 6 months, 1, 2 and 3 years later. The questionnaires cover general health, urinary symptoms and the effect of those symptoms on everyday life and sex life. The researchers will audio-record consultations where the PURSUIT study is discussed with women and interview some women to see how research is explained and understand how women manage after their treatment.

Intervention Type
Procedure/Surgery

Primary outcome measure
Patient-reported outcome measure (PROM) of continence using the International Consultation on Incontinence Questionnaire - Urinary Incontinence - Short Form (ICIQ-UI-SF) at 1 year after randomisation

Secondary outcome measures
1. Clinical subjective measure of continence (longer term) using the ICIQ-UI-SF questionnaire at 6 months, 2 and 3 years post randomisation
2. Improvement of symptoms measured using the Patient Global Impression of Improvement (PGI-I) questionnaire at 1, 2 and 3 years post randomisation
3. Procedure/operative assessment measures: assessment of procedure/operation time, estimated blood loss, hospital stay, and return to normal activity, measured at time of intervention and at 6 months post-intervention
4. Incontinence and sexual function assessed using the Pelvic Organ Prolapse/Incontinence Sexual Questionnaire (PISQ-IR) at 1, 2 and 3 years post randomisation
5. Adverse events: evaluation of treatment and retreatment, adverse events of each intervention at intervention, 6 months post intervention, and 6 months, 1, 2 and 3 years post randomisation
6. Cost-effectiveness from an NHS and societal perspective in terms of Quality-Adjusted Life Years (QALYs) and ICIQ-UI-SF at 1 year, and from a secondary care NHS perspective in terms of

QALYs at 3 years. EQ-5D-5L (used to calculate QALYs) questionnaire at 6 months, 1, 2 and 3 years post-randomisation. Secondary care resource use from Trust electronic systems (or Hospital Episode Statistics) at 1 and 3 years post-randomisation. Community-based and patient resource use questionnaire at 6 months and 1 year post-randomisation
7. Patient experiences of the intervention, assessed using qualitative interviews with patients at 6 months, 1 year and 3 years post-intervention
8. Clinician views of the intervention, assessed using qualitative interviews with clinicians around baseline

Overall study start date
01/04/2019

Completion date
04/10/2022

Reason abandoned (if study stopped)
Lack of funding/sponsorship

Eligibility

Key inclusion criteria
1. Adult women (≥18-years) with bothersome Stress Urinary Incontinence (SUI) symptoms after primary SUI surgery (including bulking injections)
2. Urodynamics to confirm recurrent or persistent SUI
3. Patient willing to consider interventional therapy
4. Patient willing to be randomised and willing to give consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
250

Total final enrolment
23

Key exclusion criteria
1. Predominant urgency incontinence
2. Pelvic organ prolapse (POP) more than or equal to stage II
3. Relevant neurological disease, disease, such as a stroke, multiple sclerosis, Parkinson’s disease, or spina bifida (diabetes mellitus is not an exclusion criterion unless it is causing diabetic

neuropathy)
4. Being treated for gynaecological or bladder cancer
5. Unresolved mesh exposure from previous midurethral tape (MUT)
6. Current pregnancy
7. Urethral diverticulum
8. Recent pelvic surgery (e.g. POP repair, stress incontinence surgery, and hysterectomy within the last 6-months)
9. Participation in another study that might influence results or increase patient burden
10. Unable to give informed consent/complete assessments
11. Previous artificial urinary sphincter (AUS) surgery

Date of first enrolment
10/12/2019

Date of final enrolment
11/07/2022

Locations

Countries of recruitment
England

Scotland

United Kingdom

Study participating centre
North Bristol NHS Trust
Southmead Hospital
Southmead Road
Westbury on Trym
Bristol
United Kingdom
BS10 5NB

Study participating centre
NHS Ayrshire and Arran
PO Box 13
Boswell House
10 Athur Street
Ayr
United Kingdom
KA7 1QJ

Study participating centre

University College London Hospitals NHS Foundation Trust
250 Euston Road
London
United Kingdom
NW1 2PG

Study participating centre
Birmingham Women's and Children's NHS Foundation Trust
Steelhouse Lane
Birmingham
United Kingdom
B4 6NH

Study participating centre
Sheffield Teaching Hospitals NHS Foundation Trust
Northern General Hospital
Herries Road
Sheffield
United Kingdom
S5 7AU

Study participating centre
Cambridge University Hospitals NHS Foundation Trust
Hills Road
Cambridge
United Kingdom
CB2 0QQ

Study participating centre
South Tees Hospitals NHS Foundation Trust
The James Cook University Hospital
Marton Road
Middlesbrough
United Kingdom
TS4 3BW

Study participating centre
Royal Cornwall Hospitals NHS Trust
Royal Cornwall Hospital
Treliske
Truro

United Kingdom
TR1 3LJ

Study participating centre
East Lancashire Hospitals NHS Trust
Royal Blackburn Hospital
Haslingden Road
Blackburn
United Kingdom
BB2 3HH

Study participating centre
Leeds Teaching Hospitals NHS Trust
St. James's University Hospital
Beckett Street
Leeds
United Kingdom
LS9 7TF

Study participating centre
Stockport NHS Foundation Trust
Stepping Hill Hospital
Poplar Grove
Stockport
United Kingdom
SK2 7JE

Study participating centre
Northern Care Alliance NHS Foundation Trust
Salford Royal
Stott Lane
Salford
United Kingdom
M6 8HD

Study participating centre
Liverpool Women's NHS Foundation Trust
Liverpool Womens Hospital
Crown Street

Liverpool
United Kingdom
L8 7SS

Study participating centre
Bedfordshire Hospitals NHS Foundation Trust
Lewsey Road
Luton
United Kingdom
LU4 0DZ

Study participating centre
Mid and South Essex NHS Foundation Trust
Prittlewell Chase
Westcliff-on-sea
United Kingdom
SS0 0RY

Sponsor information

Organisation
North Bristol NHS Trust

Sponsor details
Research & Innovation, Level 3
Learning & Research Building
Southmead Hospital
Westbury-on-Trym
Bristol
England
United Kingdom
BS10 5NB
+44 (0)117 4149330
researchsponsor@nbt.nhs.uk

Sponsor type
Hospital/treatment centre

Website
https://www.nbt.nhs.uk/

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The protocol will be available online at https://www.fundingawards.nihr.ac.uk/award/17/95/03.

The results of the study will be published in the academic press and provided to the sponsor for publishing on the sponsor's research website. The researchers will also publish results on the University of Bristol study website. They will work with their Patient and Public Involvement (PPI) partners to prepare lay summaries to enhance broader dissemination and engagement. All participants will be offered a lay summary of the main findings of the study. The trial will also be presented at national and international conferences such as the International Continence Society (ICS). This will in turn be used by the national and international community to inform practice, with incorporation into the National Institute for Health and Care Excellence (NICE) Guidelines and other international Guidelines such as those of the European Association of Urology.

The findings of the trial will be disseminated nationally through The British Association of Urological Surgeons (BAUS) and The British Society of Urogynaecology (BSUG), part of the Royal College of Obstetrics and Gynaecology, as these are the specialist bodies with the responsibility for guiding clinical practice, policy matters, research priorities, governance and training in matters related to incontinence. BAUS and BSUG are well placed to implement the findings by informing NHS policy (NICE) and by dissemination of evidence-based clinical practice to its members. The trial results will be uploaded within 1 year of the last patient last visit.

Intention to publish date
31/03/2025

Individual participant data (IPD) sharing plan

Anonymous study data will be kept securely on the University of Bristol Research Data Storage Facility (RDSF, https://www.bristol.ac.uk/acrc/research-data-storage-facility/). After the study is finished, requests for access to data should be made via the University of Bristol Research Data Repository (https://data.bris.ac.uk/data/). Requests must be via a written confidentiality and data sharing agreement (DSA) which will be confirmed/approved by the Chief Investigator. The DSA should cover limitations of use, transfer to third parties, data storage and acknowledgements. The person applying for use of the data will be scrutinised for appropriate eligibility by the research team/CI. The approved Participant Consent Form for the study includes the clause "I understand that the information collected about me will be used to support other research in the future and may be shared anonymously with other researchers".

IPD sharing plan summary

Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		03/08/2022	04/08/2022	Yes	No
HRA research summary			26/07/2023	No	No